PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 206-754-5711	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2004/007451	International filing date *(day/month/year)* 10 March 2004 (10.03.2004)	Priority date *(day/month/year)* 24 March 2003 (24.03.2003)]
International Patent Classification (IPC) or national classification and IPC [7] C07H 21/04, C12P 19/34		
Applicant CORIXA CORPORATION		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 01 October 2005 (01.10.2005)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Authorized officer Philippe Becamel Telephone No. +41 22 338 70 90

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
SUSAN L. LINGENFELTER
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SEATTLE, WA 98104

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	22 APR 2005
Applicant's or agent's file reference 609WO	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US04/07451	10 March 2004 (10.03.2004)	24 March 2003 (24.03.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C07H 21/04; C12P 19/34 and US Cl.: 435/6, 91.1, 91.2

Applicant

CORIXA CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Cynthia B. Wilder, Ph.D. Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY	International application No. PCT/US04/07451

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☒ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☒ in computer readable form

   c. time of filing/furnishing

      ☒ contained in international application as filed.

      ☒ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/07451

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-4	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-4	NO
Industrial applicability (IA)	Claims 1-4	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Wang et al (US 6482597). Regarding claims 1-3, Wang et al teach a method for determining the presence of cancer cells in a patient and monitoring the progression of lung cancer in a patient, the method comprising obtaining a biological sample from said patient, contacting said biological sample with two or more oligonucleotide primers which are unrelated to one another, wherein the oligonucleotide primer hybridize to their respective polynucleotide and the components thereof, amplifying said polynucleotides and detecting the amplified polynucleotides. The reference also teaches wherein the method may comprising contacting a biological sampled obtained from a patient with two or more oligonucleotide that hybridizes to tow or more polynucleotide that encode multiple lung tumor proteins; and comparing the amount of the polynucleotide that hybridizes to said oligonucleotides t o a predetermined cut-off value, and therefrom determining the presence or absence of lung cancer cells in the patient. In order to monitor the progression of lung cancer in a patient, the reference teaches repeating the hybridization steps as noted above at a subsequent point in time and comparing the amount of polynucleotide detected in the repetition steps with the amount detected in the step prior to repeating said hybridization (see columns 3-4, 35-36).

Regarding claim 4, Wang et al teach the method according to any of claims 1-3, wherein the polynucleotide comprises a sequence 100% identical to the sequence of SEQ ID NO: 1 (sequence SEQ ID NO: 160) and SEQ ID NO: 21 (sequence SEQ ID NO: 158). Therefore, Wang et al meet the limitations of claims 1-4 of the instant invention.

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Wang et al (WO02.004514). Regarding claims 1-3, Wang et al teach a method for determining the presence of cancer cells in a patient and monitoring the progression of lung cancer in a patient, the method comprising obtaining a biological sample from said patient, contacting said biological sample with two or more oligonucleotide primers which are unrelated to one another, wherein the oligonucleotide primer hybridize to their respective polynucleotide and the components thereof, amplifying said polynucleotides and detecting the amplified polynucleotides. The reference also teaches wherein the method may comprising contacting a biological sampled obtained from a patient with two or more oligonucleotide that hybridizes to tow or more polynucleotide that encode multiple lung tumor proteins; and comparing the amount of the polynucleotide that hybridizes to said oligonucleotides t o a predetermined cut-off value, and therefrom determining the presence or absence of lung cancer cells in the patient. In order to monitor the progression of lung cancer in a patient, the reference teaches repeating the hybridization steps as noted above at a subsequent point in time and comparing the amount of polynucleotide detected in the repetition steps with the amount detected in the step prior to repeating said hybridization (see pages 7-8, 56, 78-80, 86-98, 143-149).

Regarding claim 4, Wang et al teach the method according to any of claims 1-3, wherein the polynucleotide comprises a sequence 100% identical to the sequence of SEQ ID NO: 3 (sequence SEQ ID NO: 1868). Therefore, Wang et al meet the limitations of claims 1-4 of the instant invention.

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Wang et al (WO 02/02623). Regarding claims 1-3, Wang et al teach a method for determining the presence of cancer cells in a patient and monitoring the progression of lung cancer in a patient, the method comprising obtaining a biological sample from said patient, contacting said biological sample with two or more oligonucleotide primers which are unrelated to one another, wherein the oligonucleotide primer hybridize to their respective

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

polynucleotide and the components thereof, amplifying said polynucleotides and detecting the amplified polynucleotides. The reference also teaches wherein the method may comprising contacting a biological sampled obtained from a patient with two or more oligonucleotide that hybridizes to tow or more polynucleotide that encode multiple lung tumor proteins; and comparing the amount of the polynucleotide that hybridizes to said oligonucleotides t o a predetermined cut-off value, and therefrom determining the presence or absence of lung cancer cells in the patient. In order to monitor the progression of lung cancer in a patient, the reference teaches repeating the hybridization steps as noted above at a subsequent point in time and comparing the amount of polynucleotide detected in the repetition steps with the amount detected in the step prior to repeating said hybridization (see columns110-112 and Example 1).

Regarding claim 4, Wang et al teach the method according to any of claims 1-3, wherein the polynucleotide comprises a sequence 100% identical to the sequence of SEQ ID NO: 26 (sequence SEQ ID NO: 453). Therefore, Wang et al meet the limitations of claims 1-4 of the instant invention.

Claims 1-4 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.